DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 4, 2015

Schoelly Fiberoptic Gmbh
% Ms. Pamela Papineau
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432

Re: K143673
Trade/Device Name: CMOS Video Nasopharyngoscope System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: January 29, 2015
Received: February 5, 2015

Dear Ms. Papineau,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143673

Device Name
Schoelly CMOS Video Nasopharyngoscope System

Indications for Use *(Describe)*
The Schoelly CMOS Video Nasopharyngoscope System may only be used by persons with an appropriate medical qualification and who are acquainted with the rhino/laryngoscopic technique. The endoscope is used for endoscopic diagnosis within the nasal lumens and airway anatomy, and is intended to provide visualization via a video monitor.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Special 510(k) Summary

Preparation date:	27 February 2015
510(k) Number:	K143673
Owner's Name:	Schoelly Fiberoptic GmbH (Registration: 8043903)
Address:	Robert-Bosch-Str. 1 – 3 79211 Denzlingen Germany
Telephone Number:	+49-7666-980-0
Fax Number:	+49-7666-908-380
Contact Person:	Dr. Sandra Baumann
Subject Device Name:	Schoelly CMOS Video Nasopharyngoscope System
Trade Name:	Schoelly CMOS Video Nasopharyngoscope System
Common/Usual Name:	Video Nasopharyngoscope System
Classification Name:	EOB – Nasopharyngoscope (flexible or rigid) 21 CFR 874.4760; Class II
Predicate Device Name:	Schoelly CMOS Video Nasopharyngoscope System
Trade Name:	Schoelly CMOS Video Nasopharyngoscope System
Common/Usual Name:	Video Nasopharyngoscope System
Classification Name:	EOB – Nasopharyngoscope (flexible or rigid) 21 CFR 874.4760; Class II
Premarket Notification:	K132009 (Schoelly Fiberoptic GmbH), SE date April 09, 2014

Device Description
The Schoelly CMOS Video Nasopharyngoscope System consists of a flexible and steerable endoscope and a camera control unit (CCU) for regulation of light intensity and connection to a monitor, PC, medical video recorder or printer for image display or image documentation.

The endoscope has outer surfaces mainly made from plastic. The endoscope handle incorporates a control lever to bend the distal tip and an integrated LED light source. Light is transmitted through fiberoptic bundles illuminating the anatomy under investigation. The video signal is captured by a CMOS imaging sensor located at the tip of the endoscope shaft and transferred to the CCU.

The endoscope further incorporates a ventilation system to protect the shaft. The exhaust valve at the endoscope handle can further be used for leakage testing. For this purpose the system is accompanied by a leakage tester and accessories.

The Schoelly CMOS Video Nasopharyngoscope System is delivered in a non-sterile condition.

Indications for Use
The Schoelly CMOS Video Nasopharyngoscope System may only be used by persons with an appropriate medical qualification and who are acquainted with the rhino/laryngoscopic technique. The endoscope is used for endoscopic diagnosis within the nasal lumens and airway anatomy, and is intended to provide visualization via a video monitor.

Predicate Device
The predicate device is identical to the proposed device with the same device specifications and design, the same indications for use, and the same fundamental scientific technology. The changes described in this submission are limited to a change in the device Instructions for Use to add a validated method for high level

disinfection to the Schoelly CMOS Video Nasopharyngoscope System that was cleared for marketing by FDA in K132009. This labeling change is the only change to the device cleared in K132009.

Performance Testing

High Level Disinfection Efficacy Testing

This 510(k) contains a summary of the high level disinfection (HLD) validation conducted in accordance with ASTM E 1837 and ANSI AAMI ST 58. This validated HLD process consists of a 12 minute immersion in 0.55% orthophthaldehyde (Cidex OPA) followed by three water rinses, then air drying. The validation was conducted on devices that had previously been in clinical use to ensure "real life" conditions. Test devices and controls were inoculated in several locations with a high-titer (> 10^8 CFU/mL) suspension of an indicator organism (*Mycobacterium terrae*). The test devices were disinfected and rinsed according to the device Instructions for Use; the control devices were not disinfected after inoculation. Both the test (inoculated and disinfected) and control (inoculated only) devices were rinsed with a saline buffer solution and the rinse fluid was cultured to determine the number of viable indicator organisms remaining on each device. These data were used to derive the log-reduction in *M. terrae* achieved through the HLD process. In total, five results for microbial reduction by HLD and three inoculation control results were obtained as part of the efficacy study.

The final recovery portion of this validation demonstrated that the HLD process successfully achieved a 7.5-log reduction in the indicator organism; all of the control devices were found to have the indicator organism present at a minimum concentration of 10^6 CFU at recovery. Therefore, the HLD process was successfully validated to achieve a minimum 6-log reduction of an appropriate indicator organism.

Cytotoxicity Testing

Cytotoxicity testing performed on the test devices immediately after HLD confirmed that there was no residual disinfectant material that could adversely affect the test results by obscuring residual indicator organisms remaining after HLD.

Functional Testing

To confirm that the HLD process caused no adverse effects on the endoscope, several devices were subjected to multiple, extended HLD cycles followed by visual inspection; no damage or material degradation was observed in any of these test samples.

Conclusion

The proposed modification to the Schoelly CMOS Video Nasopharyngoscope System labeling has met all predetermined acceptance criteria as specified by applicable standards, test protocols, and/or customer inputs and does not introduce new patient or user risks. The device with the modified labeling is substantially equivalent to the device cleared in K132009.